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**WO-A-85/02778**  
**WO-A-87/04685**  
**DE-A- 1 575 011**  
**FR-A- 2 313 945**  
**GB-A- 1 162 684**

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## Description

This invention relates to inhalation devices, more particularly to improved aerosol inhalation devices containing hygroscopic drugs.

The use of aerosol inhalation devices for the administration by inhalation of medicaments in the form of powder aerosols is well known. Such devices generally comprise a housing which receives a canister of pressurised medicament. The canister is provided with a dispensing metering valve including a metering chamber and a hollow valve stem which is sealed at one end. The sealed end of the valve stem is seated in the valve and the open end locates in a spray head within the housing.

Medicament is discharged by moving the canister relative to the valve stem. This changes the dispensing metering valve from an inoperative state in which the metering chamber is isolated from the atmosphere to an operative state in which the metering chamber communicates with the atmosphere via the valve stem and an outlet orifice provided in the spray head. Usually, the valve stem is provided close to its sealed end with a lateral inlet port. In the inoperative state the inlet port is located outside the valve; in the operative state it is within the metering chamber and medicament can pass from the chamber through the inlet port, the valve stem, the spray head and the outlet orifice into the housing from where it can be inhaled by a user inhaling at a mouthpiece formed in the housing.

A problem which can occur when devices of this type are used to administer hygroscopic medicaments is blockage.

WO-A-87/04685 and GB-A-1162684 disclose aerosol valves having a valve stem with an inlet port which is concealed within a dispensing container. WO-A-85/02778 and FR-A-2313945 disclose aerosol inhalation devices having a mouthpiece portion and a canister containing portion delimited by a barrier. The problem of blockage associated with dispensing hygroscopic medicaments is not addressed by any of these documents.

The problem of blockage is solved, according to the invention, by an aerosol inhalation device, comprising a mouthpiece and a canister of pressurised hygroscopic medicament, the canister being fitted at one end with a dispensing metering valve having a valve stem provided with an inlet port; characterised in that a protective cap provided with a frusto-conical central portion through which the valve stem protrudes is fitted over the end of the canister fitted with the valve, the arrangement being such that the cap shields the inlet port from a user's breath.

By "hygroscopic medicament" we mean a medicament which takes up significant amounts of

water when in a moist atmosphere, for example one which at 90% relative humidity (being approximately a lower value for the relative humidity found in human breath) takes up more than 8% of its own weight of water. Examples of such medicaments include sodium cromoglycate and nedocromil sodium.

The aerosol inhalation devices of the invention have the advantages that they do not become blocked or block less frequently, so that a canister of medicament can be exhausted without the danger of the device being discarded prematurely because the patient mistakenly believes that the canister is empty or because it cannot readily be unblocked; there is a greatly reduced risk of plugs of medicament forming in the devices which are subsequently inhaled by the patient - this is especially dangerous for patients who have breathing difficulties and who are most likely to be using aerosol inhalation devices; the devices are more hygienic because there are fewer or no medicament accretion surfaces which bacteria may colonize; and they need to be cleaned less frequently - cleaning being a difficult task for patients who have unsteady hands.

We prefer arrangements in which the cap is able to brush the surface of the valve stem and thus help further prevent blockage and the build up of accretions of medicament.

The cap may be of elastomeric material.

The cap may be provided with means for engaging the aerosol inhalation device in which the pressurised medicament canister is to be used. The engaging means may be, for example, a keyway or recess formed on the cap which is adapted to receive a key or protrusion formed on the aerosol inhalation device. This has the advantage that a given inhalation device fitted with a key or protrusion may only be used with pressurised aerosol canisters fitted with a cap having a complementary keyway or recess, thereby improving hygiene, reducing medicament misuse, and reducing the risk of accidental administration of the wrong medicament. Of course, the opposite configuration may be envisaged in which the keyway or recess is formed on the aerosol inhalation device and the key or protrusion is formed on the cap.

A preferred embodiment of the invention will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a vertical section through a dispensing metering valve of an aerosol inhalation device having a cap to shield the lateral inlet port.

Figure 1 shows a dispensing metering valve from a medicament canister. The dispensing metering valve comprises a valve body 1 which encloses a metering chamber 2 which is closed at its

upper and lower ends by seals 3 and 4 respectively. A valve stem 5 is centrally disposed in the chamber 2 and cooperates with the seals 3 and 4. The valve stem 5 is provided with a discharge vent 6 along part of its long axis such that the end of the valve stem 5 remote from the valve is open, and a lateral inlet port 7 transverse to and communicating with the discharge vent 6. The valve stem 5 is moveable axially, and its movement changes the valve from an inoperative state (illustrated) in which the chamber 2 is isolated from the atmosphere while the chamber communicates with the contents of the canister, and an operative state in which the contents of the chamber 2 can be discharged to the atmosphere through the discharge vent 6 via the inlet port 7. The valve is held onto the canister by means of a ferrule 9.

The inlet port 7 is protected from a user's breath, and cleaned by, a cap 10 having a frusto-conical protrusion 8 which surrounds the portion of the valve stem 5 including the inlet port 7.

Cap 10 has a snap-fit with the rim of ferrule 9.

#### Claims

1. An aerosol inhalation device, comprising a mouthpiece and a canister of pressurised hygroscopic medicament, the canister being fitted at one end with a dispensing metering valve having a valve stem (5) provided with an inlet port (7); characterised in that a protective cap (10) provided with a frusto-conical central portion (8) through which the valve stem protrudes is fitted over the end of the canister fitted with the valve, the arrangement being such that the cap (10) shields the inlet port (7) from a user's breath.
2. An aerosol inhalation device according to claim 1, characterised in that the cap (10) brushes the surface of the valve stem (5).
3. An aerosol inhalation device according to claim 1 or claim 2, characterised in that the medicament is sodium cromoglycate or nedocromil sodium.
4. A cap (10) as defined in claim 1 or claim 2.

#### Patentansprüche

1. Aerosol-Inhalationsgerät, das ein Mundstück und einen Dosenbehälter mit unter Druck stehendem hygroskopischen Medikament aufweist, wobei der Dosenbehälter an einem Ende mit einem Abgabedosierventil ausgerüstet ist, das einen Ventilschaft (5) hat, der mit einer Einlaßöffnung (7) versehen ist; dadurch ge-

kennzeichnet, daß eine Schutzkappe (10), die mit einem kegelstumpfförmigen zentralen Teil (8) versehen ist, durch den der Ventilschaft vorsteht, über dem das Ventil aufweisenden Ende des Dosenbehälters angebracht ist, wobei die Anordnung derart ist, daß die Kappe (10) die Einlaßöffnung (7) gegen den Atem eines Benutzers abschirmt.

2. Aerosol-Inhalationsgerät nach Anspruch 1, dadurch gekennzeichnet, daß die Kappe (10) über die Oberfläche des Ventilschaftes (5) streicht.

3. Aerosol-Inhalationsgerät nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Medikament Natriumcromoglykolat oder Nedocromilnatrium ist.

4. Kappe (10), wie in Anspruch 1 oder 2 definiert.

#### Revendications

1. Inhalateur d'aérosols comprenant une embouchure et une cartouche de médicament hygroscopique sous pression, la cartouche étant pourvue à une extrémité d'une valve doseuse de distribution comportant une tige de valve (5) pourvue d'une lumière d'admission (7), caractérisé en ce qu'un chapeau de protection (10) pourvu d'une partie centrale tronconique (8) traversée par la tige de valve est adapté sur l'extrémité de la cartouche pourvue de la valve, l'agencement étant tel que le chapeau (10) protège la lumière d'admission (7) de l'haléine d'un utilisateur.
2. Inhalateur d'aérosols suivant la revendication 1, caractérisé en ce que le chapeau (10) balaye la surface de la tige de valve (5).
3. Inhalateur d'aérosols suivant la revendication 1 ou 2, caractérisé en ce que le médicament est du cromoglycate de sodium ou du nedocromil sodique.
4. Chapeau (10) suivant la revendication 1 ou 2.

*Fig. 1.*

